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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,646

02/23/2004

Joseph P. Errico

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LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK  
600 SOUTH AVENUE WEST  
WESTFIELD, NJ 07090

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/784,646	<b>Applicant(s)</b> ERRICO ET AL.	
	<b>Examiner</b> Brian E. Pellegrino	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21 is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10,11,14-18 and 20 is/are rejected.
- 7) ☒ Claim(s) 2,9,12 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,4,5,10,11,15-18,20 are rejected under 35 U.S.C. 102(a) as being anticipated by Grunberg et al. (WO 02/71986). Figs. 4a,4b show apparatus for distracting intervertebral space comprising a shaft within the sides (402,404) with at least two distal extensions (407,409) coupled to the shaft. The distal extensions have a fixed dimension from one another in the same plane, but the intermediate portions of the extensions move toward and separate via the distractor mechanism **416** in the intermediate location. It can also be seen that there are pins **410** located centrally or between the dimensions of the distal end of the extensions and coupled thereto to the plates, page 18. Regarding claim 10, it can be seen the distractor mechanism includes a pin that can move proximally and distally to increase and decrease the separation between the intermediate portions of the extensions to act as a fulcrum. It can also be seen there is a bifurcated trial with two halves **202** coupled to the distal extensions. The examiner is interpreting the claimed elements "bifurcated trial" in this way: two split halves capable of being inserted into the intervertebral space. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054,1055. The external shape is capable of "approximating" the external disc shape of

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the artificial intervertebral disc. Regarding claims 4,5 the trial halves have a smooth outward facing surface, see Fig. 7. Regarding claim 11, please note the functional limitation "biased" carries no weight in the absence of any distinguishing structure. Regarding claim 16,18,20 there is a control device **414** or knob coupled to the apparatus that can be rotated. With respect to claim 17, it can be interpreted that hinge structure (416) is a control device to maintain separation of the trial halves.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grunberg et al. (WO 02/71986) in view of Baumgartner (5370697). Grunberg et al. is explained above. However, Grunberg et al. fail to teach a dome outer surface on the implant. Baumgartner shows (Fig. 5) a vertebral contact element **44** having a resting shape of a dome convexly extending from an orthopedic device **2**. It would have been obvious to one of ordinary skill in the art to utilize a dome outer surface on the implant as taught by Baumgartner with the apparatus of Grunberg et al. such that it can be placed within the vertebrae's contour.

Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grunberg et al. (WO 02/71986) in view of Ripple et al. (4566466). Grunberg et al. is explained supra. However, Grunberg et al. fail to teach markings for sizing. Ripple et al. teach (Figs. 6,7) markings for sizing a disc to be implanted. It would have been

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obvious to one of ordinary skill in the art to use markings as taught by Ripple et al. with the apparatus of Grunberg et al. such that the proper implant can be determined for the patient. It is well known in the art to use markings on shafts and would have been obvious to one of ordinary skill in the art to incorporate markings on a shaft of Grunberg et al. It would have been an obvious expedient to modify the dimensions of the disc size, since using 13mm-20mm would only involve routine skill in the art of a surgeon in estimating the intervertebral space and the proper size of the implant to be placed therein. One of ordinary skill in the art clearly can optimize the sizes as taught by Ripple or the claimed range of 13-20mm in claim(s) 8 because both apparatus perform the same function of finding the appropriate size for the patient and would have predictable results on filling the space between vertebrae of a patient.

### ***Response to Arguments***

Applicant's arguments filed 3/19/09 have been fully considered but they are not persuasive. Applicant argues that Grunberg does not disclose pins coupled to the plates. However, the Examiner respectfully disagrees and as mentioned above is illustrated in the Figs. 4a-4c and page 18 of the disclosure.

### ***Allowable Subject Matter***

Claims 2,9,12,19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 21 is allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brian E Pellegrino/  
Primary Examiner, Art Unit 3738